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| GeneXpert CT/NG Assay Quality Control |
| **Purpose** | This procedure provides instructions for Quality Control procedures required for the Xpert CT/NG Assay.  |
| **Policy Statements** | This procedure applies to all employees that work in microbiology. |
| **Sample** | **New Lot/Shipment and Monthly Quality control:*** Microbiologics Cepheid Xpert CT/NG negative controls
* Microbiologics Cepheid Xpert CT/NG positive controls

**Engineering control (monthly):*** Swab collected with a CT/NG Vaginal/endocervical Specimen Collection Kit

**Instrument Performance Verification after repairs:*** One known positive and one known negative patient sample OR Positive and Negative External Control swabs
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| Frequency | -Every 30 days-Receipt of new shipments-Receipt of new lots-Drift in results (e.g., increasing/decreasing positivity rates)-Potential contamination (negative control)-After Xpert check or drastic system maintenance-Wipe testing: Monthly  |
| **Special Safety Precautions** | Microbiologists/virologists are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology*and *Virology Policy Manual***:**1. *Biohazard Containment*
2. *Safety in the Microbiology/Virology Laboratory*
* *Biohazardous Spills*
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| **Materials** |

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| Reagents | Supplies | Equipment |
| * Microbiologics Cepheid Xpert CT/NG positive and negative controls
* Fibroblasts
* 10% bleach
* 70% ethanol
 | * CT/NG Vaginal/endocervical Specimen Collection Kits
* Xpert CT/NG Assay cartridges
* Transfer pipettes
* Simple racks
* Cartridge transfer tray

Store kits at 2-28°C. Kits are stable until the expiration date printed on the outer box.  | * Biosafety Hood
* Cepheid GeneXpert Instrument and computer
* Printer
* 1000uL pipette
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| **Procedure** | **New Lot/Shipment and Monthly Quality control:**1. Clean hood and supplies: 10% bleach followed by 70% ethanol.
2. Change gloves.
3. Obtain two test cartridges and two vaginal collection sample tubes.
4. Label cartridges and collection tubes for the positive and negative controls.

NOTE: Set up the positive control first.1. Open the control swab.
2. Insert the swab into the collection tube, lift it up (about 2cm from the bottom), and break the shaft off using an absorbent biohazard pad (orange) as a barrier on the top of the tube.
3. Vortex the vial for 10 seconds.
4. Change gloves in-between processing of controls AND before moving to the instrument.
5. Run cartridges as patient samples. (see Xpert CT/NG Assay procedure)

NOTE: Under the “Test Type” field select “Positive Control 1” or “Negative Control 1”.1. Clean hood with 10% bleach followed by 70% ethanol.
2. Document QC in the GeneXpert CT/NG Assay binder.

NOTE: Before reporting patient results, all controls must yield valid results.**Engineering control:**1. Using a swab from a CT/NG Vaginal/endocervical Specimen Collection Kit, swab the processing hood surface, 1000uL pipette, counter around the GeneXpert instrument (including the keyboard, mouse, and scanner), and door handles on the instrument.
2. Dip swab into a sterile suspension of fibroblasts.
3. Break swab off into a CT/NG Vaginal/endocervical Specimen Collection device.
4. Process and run as a patient sample.
5. Document testing in the GeneXpert CT/NG binder.

NOTE: In the event of positive result notify the tech specialist, decontaminate, and re-test.  |
| **Interpretation and Documentation** | 1. Ensure that the printer is turned on.
	1. Reports will print automatically.
2. Click on **View Results** on the top drop-down menu bar and select **View Test**.
3. Select the result you would like to review: Click **OK**.
4. Review result interpretations and amplification curves for exponential growth.
	1. NOTE: SAC and SPC do not need to pass for a positive result to be valid.
	2. NOTE: SAC and SPC do need to pass for a negative result to be valid.

1. Click on the **Errors** tab to ensure no errors occurred during testing. (Section 9.18.2 in Operator Manual provides error code descriptions)

**Reasons to retest:**1. An INVALID result. This may indicate:
	1. The sample was inadequate.
	2. The sample was not properly processed.
	3. PCR was inhibited.
2. An ERROR result. This may indicate:
	1. The reaction tube was filled improperly.
	2. A reagent probe integrity problem was detected.
	3. The maximum pressure limit was exceeded.
	4. A valve positioning error was detected.
3. NO RESULT:
	1. This result indicated that insufficient data were collected. (e.g. test stopped while in progress or power failure occurred.

NOTE: Record any failures on the “GeneXpert Service and Error Log” log. **Valid Results:*** Microbiologics Cepheid Xpert CT/NG positive control: CT/NG detected
* Microbiologics Cepheid Xpert CT/NG negative control: CT/NG not detected
* Engineering control: CT/NG not detected

NOTE: If there is a QC failure, document observation and correction action. Report QC problems that cannot be resolved to the tech specialist. For repeated failures contact Cepheid Technical Support. Do not report patient results until problem is resolved. |
| **References** | 1. Cepheid Inc, Sunnyvale, CA: Xpert CT/NG Assay Package Inster 301-0234, Rev. D, March 2016.
2. CAP Microbiology Checklist, College of American Pathologists, 325 Wakegan Road, Northfield, IL 60093-2750, 08/17/2016.
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| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | J. Laramie/H. Stefan | 04.16.2018 | Initial Version |
| 2 | J. Laramie  | 09.01.2018 | Switched from ZeptoMetrix control product to Microbiologics  |
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| **Archived by:** |  | **Archived Date:** |  |